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(54) Title: METHOD AND DEVICE FOR PRODUCING PRODUCTS IN WEB FORM

(57) Abstract: The present invention pertains to a method for producing products in web form in which a coating mass comprising one or more active-ingredients first is applied onto the surface of a transfer support web, subsequently the composite of transfer support web and coating is treated thermally, then an intermediate support material is applied onto the coating and finally the product in web form comprising the intermediate support material and the coating are separated from the transfer support web, wound up and stored. The transfer support web used thereby is performed as an endless loop. The transfer support web performed as an endless loop is recirculated to be applied again with the coating after its regeneration. The invention pertains also to a device suitable for performing the method.

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Method and Device for Producing Products in Web Form

Background of the Invention

5 The present invention pertains to a method and a device for producing products in web form, in particular, thin films by coating a coating mass comprising organic raw materials in an aqueous basis on a reusable support web, drying the products and transferring the dried products onto a reusable intermediate support material.

10 Flat administration forms to be applied in the oral region and on mucous membranes of the mouth are known. US patent 3,444,858 describes medicament strips based on a gelatin-like material. Also, pharmaceutical products in the form of a film have already been described in the early 70s. DE-A 24 49 865 described medicinal active substance carriers in the form of a film, containing different active
15 substances and active substance concentrations.

US patent 4,128,445 discloses technical solutions in loading of carrier material with active substances and, in this context, goes into the subsequent addition of active substance preparations by applying them onto pre-fabricated film-shaped
20 preparations. The document describes loading methods in dry and moist form aiming at achieving a uniform, subsequent distribution of active substance on a layer.

Canadian patent application No. 492 040 describes a process for manufacture of film-shaped preparations employing active substance along with gelatin, agar,
25 gluten, carboxyvinyl polymer, polyhydric alcohol, vegetable mucilage, wax or water.

Also known are proposals for application of active substance-loaded films or foils outside the pharmaceutical field. Thus, in EP-A 219 762 a water-soluble film of starch, gelatin, glycerol or sorbite is disclosed, which is coated using the roll coating
30 method. In this connection, it is stated that such dosing forms may also be produced employing ingredients of chemical reagents, aromatics and the like.

DE-A 36 30 603 provides for a flat dosage form, on a carrier material (release film), to be peelable in doses.

5 Drug containing film-shaped systems and their advantages are further known from US patent 5,047,244. These systems comprise a double-layered structure of a water swella-
ble layer and a non-water-swella-
ble barrier film. The use of polymers such as polyethylene glycol, the use of colloidal silicon dioxide, of bioadhesive (e.g. carboxy-
functional) polymers, but also of polyvinyl alcohol, and of a number of other auxiliary
substances is likewise known from the above publication.

10 A preparation suitable for making film-shaped aromatics-containing preparations is described by EP-A 460 588. A composition comprising 20 to 60 weight-% of film former, 2 to 40 weight-% of gel former, 0.1 to 35 weight-% of active substance or
aromatic, and a maximum of 40 weight-% of an inert filling agent is regarded as
15 affording particular advantages. As a gel former, polyvinyl alcohol is mentioned besides other ingredients. However, as it turns out, the gel-forming properties of polyvinyl alcohol are only partially compatible with the film formers mentioned in this
written document. A portion of 20 weight-%, and more, of film-former - mostly a
sugar derivative, polyethylene glycol, etc. - lead to considerable loss of aroma
20 occurring already in thin layer drying, which is part of the production process.

The films or coatings to which the instant invention is related are based on organic
materials or on a mix of such substances. These are preferably water-soluble
substances. Such organic raw materials include polymers such as polyvinyl alcohol,
25 pyrrolidone, cellulose derivatives, polyvinyl acetate, polyethylene glycol,
carrageenan, xanthan, gelatine and other water-soluble polymers known to
the skilled artisan, as well as mixtures and copolymers of such substances. If
desired, such films or coatings may also include fillers such as mannitol, lactose,
phosphate, glucose, sorbitol etc., active substances such as drugs, aroma
30 substances, menthol etc., sweeteners such as cyclamate, flavours such as
aroma, and other ingredients, including in some cases volatile ingredients.
These films may also have mucoadhesive properties.

Usually, the films and coatings are produced by means of casting methods or reverse coating methods. The manufacture of thin films or coatings is accomplished according to the present invention in that initially a coating mass is prepared containing organic substances which are suitable for forming a film, or a coating, for instance, polymers such as polyvinyl alcohol, polyvinyl pyrrolidone, cellulose derivatives, polyvinyl acetate, polyethylene glycol, alginate, carrageenan, xanthan, gelatine and other water-soluble polymers known to the skilled artisan, as well as mixtures or copolymers of such substances. Preferably, these substances are completely or partially dissolved or dispersed in water. Apart from water, other solvents may be used as well, e.g. alcohols such as methanol, ethanol, propanol or solvent mixtures such as water-alcohol mix.

The coating composition may further comprise various additives, e.g. fillers such as mannitol, lactose, calcium phosphate, glucose, sorbitol etc., and/or active substances such as drugs, aroma substances, menthol etc., and/or sweeteners such as cyclamate, flavours such as glutamate, and other ingredients, including in some cases volatile ingredients.

The coating mass thus obtained is subsequently applied to a web-shaped support material, using the casting method or reverse coating method. As support material, a web or sheet of paper, plastic, metal or a composite of two or more of these materials may be used.

The product web may, for example, have a width of about 0.1 m to about 2 m. Preference is given a width in the range of from 0.5 to 1.6 m. The films or coatings applied to the support layer are preferably thin, that means, their thickness ranges of from about 10 to 500 μm , preferably from 50 to 200 μm .

The coated support material, i.e. the composite of support and coating composition, is thereafter transferred into a drying device (drying oven) and transported through the same, preferably continuously.

The dried composite is then wound up and stored.

5 The above-described method, however, has the disadvantage that parts of the active-ingredient diffuse from the coating into the support material during the contact period. For that reason, used support material cannot be used again for the preparation of the same or other products in web form, since an unpredictable quantity of active-ingredient disappears from the coating or diffuses back from the support material into the coating during the contact period. Thus, big amounts of waste support material arise during the conventional process making the
10 preparation expensive and environmentally less favourable.

Summary of the Invention

15 The object of the present invention was to provide a method and a device for the preparation of products in web form in which reduced amount of waste transfer film occurs, thus, saving costs and environmental effort, as well.

20 The invention, accordingly, pertains to a method for producing products in web form in which a coating mass first is applied onto the surface of a transfer support web, subsequently the composite of coating mass and transfer support web is dried thermally, then an intermediate support material is applied on the surface of the coating and finally the composite of the intermediate support material and the ~~coating~~ is separated from the transfer support web, wound up and stored, wherein
25 the transfer support web used is preferably an endless loop.

~~Detailed~~ Description of the Invention

30 In the preferred embodiment of the present invention, the transfer support web is comprised of a solid material such as polymer material having sufficient mechanical ~~strength~~ and heat resistance or the transfer film is comprised of a composite ~~material~~ of paper with a polymer layer on top or a metal foil or a composite material or metal and polymer film such as metallized polymer film.

The endless loop used as the transfer support web in the present invention, preferably, has a uniform thickness over its total length to avoid fluctuations in the thickness of the product in web form applied thereon.

5 The composite of the coating and the transfer support web is dried by thermal treatment in a heating device, preferably in a hot air chamber at temperatures in the range of from 40 to 120 °C, preferred from 50 to 100 °C. It is also possible to conduct the thermal treatment in multiple steps through multiple heating devices at different temperatures. The total time period for thermal treatment lies within the
10 range of from 5 s to 60 s, preferably from 10 s to 50 s.

After the thermal treatment, the humidity of the product in web form is adjusted in the appropriate range of from about 20 to 60 %. The composite is then fed to a laminating- or cooling device, where an intermediate support material coming from
15 a storage roll is applied onto the coating. The intermediate support material is preferably fixed with a strip of an adhesive at the starting point. Possible adhesives are hot melt adhesives or pressure sensitive adhesives which are commercially available. The laminating- or cooling device comprises essentially a cooling drum on which the laminate of intermediate support material, coating and transfer support
20 web is pressed together to maintain a sufficient connection.

The intermediate support material may be comprised of paper or paper like material like cardboard, however, it is also possible to use polymer films as intermediate support material.

25 Leaving the laminating station the transfer support web is separated from the laminate of intermediate support material, coating and transfer support web by means of rolls. The separation of the transfer support web is easy, if the humidity of the coating is adjusted in the appropriate range.

30 The ready prepared product in web form comprising the intermediate support material and the coating is wound up and stored for its final destination

subsequently after its separation from the transfer support web.

5 The separated transfer support web, however, is fed to a regeneration station. The regeneration of the transfer support web comprises at least mechanical removal of every adhering foreign particles and vacuum cleaning of the mechanical treated transfer support web. Additionally, the regeneration can be combined with a wet or chemical decontamination comprising washing the transfer support web with clear water or organic solvent or cleaning it with detergents and subsequent drying in hot air. In any case, the regenerated transfer support web is wound up and fed back or
10 alternatively immediately fed back to the coating station, to be applied again with the coating, in this manner circulating endless according to the method of the instant invention.

15 The present invention pertains also to a device for performing the method producing products in web form according to the transfer method. The device comprises at least a coating station, a laminating or cooling station, separating rolls and a regeneration station for a transfer support web, whereby the transfer support web is performed as an endless loop.

20 The device in its preferred embodiment is much better illustrated for the skilled artisan by means of the attached picture of drawing.

Fig. 1 shows, schematically, a machine of the present invention in side view.

25 Especially, Fig. 1 shows the coating station 1, wherein the coating is applied onto the transfer support web, and the heating device 2, wherein the transfer support web coated with the coating is thermally treated. The heat treated transfer support web applied with the coating reach at point "A" the lamination station comprising a big cooling drum 3. Simultaneously, an intermediate support material coming from a storage roll 8 is laminated with the coating at point "A". Before reaching point "A",
30 the support layer is fixed with a strip of an adhesive at the starting point "B". After the cooling drum 3, separating rolls 4, 5, 6 and 7 are arranged. At the last separating

roll 7 the transfer support web is separated from the product in web form. The product in web form comprising the intermediate support material and the coating is fed to an invisible winding station, whereas the transfer support web reaches the regeneration station 9 where mechanical treatment and vacuum cleaning occurs.

5 The possible recirculation of the regenerated transfer support web to the coating station 1 is shown in the right part of the picture, whereas the alternative of winding up and using again of the transfer support web is not illustrated in the picture.

10 The present invention is a novel and economic method to produce products in web form, especially under cost saving conditions, since a minimum of waste material is caused due to the recirculation of the transfer support web. According to the prior praxis, all used transfer support web had to be disposed as waste material.

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Patent Claims

1. Method for producing products in web form in which a coating mass first is applied onto the surface of a transfer support web, subsequently the composite of transfer support web and coating is treated thermally, then an intermediate support material is applied on the coating and finally the composite of intermediate support layer and coating separated from the transfer support web, wound up and stored, wherein the transfer support web used is performed as an endless loop.
2. Method according to claim 1, wherein the transfer support web is comprised of a solid material such as polymer material or of a composite material of paper with a polymer layer on top or a metal foil or a composite material of metal and polymer film such as metallized polymer film.
3. Method according to claim 1, wherein the endless loop used as the transfer support web has a uniform thickness over its total length.
4. Method according to claim 1 wherein the coating is prepared by mixing its ingredients in an aqueous medium.
5. Method according to claim 1, wherein the coating is applied to the transfer support web in a coating station by a casting method or a reverse coating method in a thickness in the range of from 10 to 500 μm , preferably from 50 to 200 μm .
6. Method according to claim 1, wherein the transfer support web and the coating is thermally treated in a heating device.
7. Method according to claim 6, wherein the thermal treatment is performed in a hot air chamber at temperatures in the range of from 40 to 120 $^{\circ}\text{C}$.

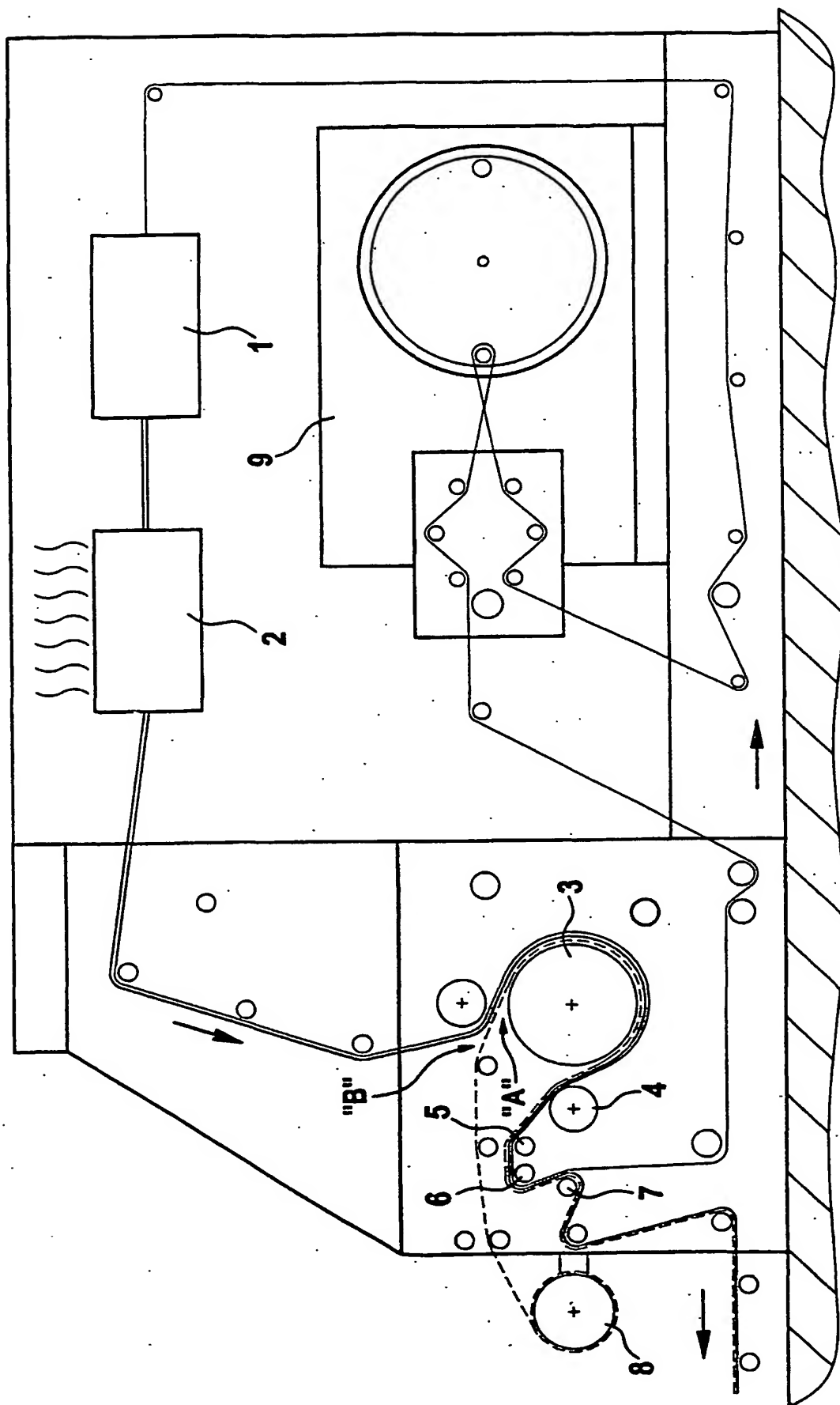
8. Method according to claim 7 wherein the thermal treatment is performed at temperatures in the range of from 50 to 100 °C.
- 5 9. Method according to claim 1, wherein the thermally treated composite comprising the coating and the transfer support web are fed to a laminating- or cooling device, where an intermediate support material coming from a storage roll is applied onto the coating.
- 10 10. Method according to claim 1, wherein the intermediate support material is fixed with a strip of an adhesive at the starting point.
11. Method according to claim 1, wherein the intermediate support material is comprised of paper or paper like material like cardboard, or polymer film.
- 15 12. Method according to claim 1, wherein the separated transfer support web is fed to a regeneration station, wherein regeneration of the transfer support web is performed.
- 20 13. Method according to claim 12, wherein the regeneration of the transfer support web comprises at least mechanical removal of adhering foreign particles and vacuum cleaning of the mechanical treated transfer support web.
- 25 14. Method according to claim 13, wherein the regeneration is combined with a wet or chemical decontamination comprising washing the transfer film with clear water or organic solvent or cleaning it with detergents and drying it in hot air.
- 30 15. Method according to claim 1, wherein the regenerated transfer support web is immediately recirculated to the coating station, to be applied again with the coating.

16. Method according to claim 1, wherein the regenerated transfer support web is first wound up and after storage recirculated again to the coating station, to be applied again with the coating.

5 17. Device for performing the method for producing products in web form comprising at least a coating station (1), a laminating- or cooling station (3), separating rolls (4, 5, 6, 7) and a regeneration station (9) for a transfer support web, whereby the transfer support web is performed as an endless coil.

10 18. Device according to claim 17 comprising additionally a heating device (2) between the coating station (1) and the laminating- or cooling station (3).

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A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/70 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 67694 A (ELECTROSOLS) 16 November 2000 (2000-11-16) claims figures 1-3	1-18
A	WO 01 28904 A (LTS) 26 April 2001 (2001-04-26) claims figures 5-7	1-18
A	US 4 128 445 A (A. STURZENEGGER ET AL.) 5 December 1978 (1978-12-05) cited in the application claims figures 3,5	1-18
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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